EPA. 1998. Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F
(Published on May 14, 1998, Federal Register 63(93):26846-26924)

This document covers a lot of similar ground to the stressor identification document and often in a less useful way so I have not summarized it as thoroughly.

Risk assessment consists of a number of steps: problem formulation, analysis, risk characterization, risk communication.

Problem formulation is a process for generating and evaluating preliminary hypotheses about why ecological effects have occurred, or may occur, from human activities. It provides the foundation for the entire ecological risk assessment. Early in problem formulation, objectives for the risk assessment are refined. Then the nature of the problem is evaluated and a plan for analyzing data and characterizing risk is developed. Any deficiencies in problem formulation will compromise all subsequent work on the risk assessment.

Problem formulation results in three products: (1) assessment endpoints that adequately reflect management goals and the ecosystem they represent, (2) conceptual models that describe key relationships between a stressor and assessment endpoint or between several stressors and assessment endpoints, and (3) an analysis plan.

Assessment endpoints are explicit representations of the actual environmental value(s) that (are) to be protected. Assessment endpoints are critical to problem formulation because they structure the assessment to address management concerns and are central to conceptual model development. They should be measurable ecosystem characteristics that adequately represent management goals. Three principal criteria are used to select ecological values that may be appropriate for assessment endpoints: (1) ecological relevance, (2) susceptibility to known or potential stressors, and (3) relevance to management goals.

Once ecological values are selected as potential assessment endpoints, they need to be operationally defined. There two aspects to this definition: 1. identification of the specific valued ecological entity (e.g., species, functional group, community, etc.); 2. the attribute of the entity that is important to protect. For an assessment endpoint to serve as a clear interpretation of the management goals and the basis for measurement in the risk assessment, both an entity and an attribute are required.

A conceptual model in problem formulation is a written description and visual representation of predicted relationships between ecological entities and the stressors to which they may be exposed. Multiple conceptual models may be generated to address several issues in a given risk assessment. Conceptual models consist of two components: 1. a set of hypothesized relationships that link stressors with assessment endpoints; and 2. a diagram illustrating these relationships.

The analysis of stressors and risk may range from quantitative to qualitative, depending on the stressor(s), the quality of available data, and the scope of the assessment. For chemical stressors, estimation of effects often entails extrapolation from test organisms to the organism of interest. For physical stressors, the may directly effect the assessment endpoint (e.g., loss of wetland acreage). In many cases, however, secondary effects (e.g., decline of wildlife populations that depend on wetlands) may be the principal concern.

QuickTime™ and a
decompressor
are needed to see this picture.

Flow chart of the risk assessment process.

To characterize ecological effects, the effects elicited by a stressor are described, linked to the assessment endpoints, and evaluated against different stressor levels. The data are evaluated to specify the effects that are elicited, verify that they are consistent with the assessment endpoints, and confirm that the conditions under which they occur are consistent with the conceptual model. Once the effects of interest are identified, an ecological response analysis is used to evaluate how the effects change with different stressor levels and the stressors are then linking the effects with the assessment endpoint. Conclusions are summarized in a stressor-response profile.

Conclusions presented in the risk characterization should clearly define the risks associated with various stressors. If the risks are not sufficiently defined to support a management decision, alternatives include another iteration of the risk assessment, reevaluation of the conceptual model (and associated risk hypotheses) or additional studies to improve the risk estimate. If a management action is implemented, a monitoring program may help managers evaluate its effectiveness [Note: this is the function of adaptive management.].

Risk estimates can be developed using one or more of the following techniques: (1) field observational studies, (2) categorical rankings, (3) comparisons of single-point exposure and effects estimates, (4) comparisons incorporating the entire stressor-response relationship, (5) incorporation of variability in exposure and/or effects estimates, and (6) process models that rely partially or entirely on theoretical approximations of exposure and effects.

Field observations provide a useful foundation for risk assessments because they represent the actual conditions related to a particular case. A primary qualification is whether a causal relationship between stressors and effects is supported. Unless causal relationships are carefully examined, conclusions about effects that are observed may be inaccurate because the effects are caused by factors unrelated to the stressor(s) of concern.

Categorical ranking employs professional judgment or other qualitative evaluation techniques to rank risks using categories, such as low, medium, and high, or yes and no. This approach is most frequently used when exposure and effects data are limited or are not easily expressed in quantitative terms. For example, Harris et al. (1994)[1] evaluated risk reduction opportunities in Green Bay (Lake Michigan), Wisconsin, by employing an expert panel to compare the relative risk of several stressors against their potential effects. Mathematical analysis based on fuzzy set theory was used to rank the risk from each stressor from a number of perspectives, including degree of immediate risk, duration of impacts, and prevention and remediation management. The results ranked potential environmental risks from stressors based on best professional judgment.

Single point exposure comparisons can be made when sufficient data are available to quantify exposure and effects estimates. The simplest approach for comparing the estimates is a ratio, such as exposure concentration divided by effects concentration. Quotients are commonly used for chemical stressors, where reference or benchmark toxicity values are widely available. The principal advantages of the quotient method are that it is simple and risk managers are familiar with its application. It provides an efficient, inexpensive means of identifying high- or low-risk situations that can allow risk management decisions to be made without the need for further information. Quotients can also been used to integrate the risks of multiple chemical stressors: quotients for the individual constituents in a mixture are generated by dividing each exposure level by a corresponding toxicity endpoint (e.g., LC50, EC50, NOAEL). Although the toxicity of a chemical mixture may be greater than or less than the toxicities of individual constituents, a quotient addition approach assumes that toxicities are at least approximately additive. A quotient can be useful in answering whether risks are high or low but may not be helpful in an incremental quantification of risks. For

[1] Harris, HJ; Wenger, RB; Harris, VA; Devault, DS. (1994) A method for assessing environmental risk: a case study of Green Bay, Lake Michigan, USA. Environ Manage 18(2):295-306.

example, knowing that a risk mitigation approach will reduce a risk quotient from 25 to 12 may not be easily interpreted in terms of effects on an assessment endpoint.

If a curve relating the stressor level to the magnitude of response is available, then risk estimation can be based on the entire stressor/response pathway and risk can be related to virtually any level of exposure. The effects curve allows the manager to predict changes in the magnitude and likelihood of effects for different exposure scenarios. Comparing exposure and stressor-response curves provides a predictive ability lacking in the quotient method. Like the quotient method, however, limitations from the problem formulation and analysis phases may limit the utility of the results.

If the response curve to stressor exposure includes estimates of uncertainty then this can be incorporated into the risk assessment to help evaluate different management responses.

Process models are mathematical expressions that represent our understanding of the mechanistic operation of a system under evaluation. They can be useful tools in both analysis and risk characterization. It is useful to distinguish between analysis process models, which focus on exposure or effects evaluations, and risk estimation process models, which integrate exposure and effects information.

A major advantage of using process models for risk estimation is the ability to consider "what if" scenarios and to forecast beyond the limits of observed data. Process models can also consider secondary effects, unlike other risk estimation techniques. In addition, some process models can forecast the combined effects of multiple stressors.

It is important that risk assessors thoroughly represent all lines of evidence developed in the risk assessment. The conclusions of a risk assessment may be strengthened when several lines of evidence can be used to interpret and compare risk estimates. Analysts should consider three principal sets of factors when evaluating lines of evidence: (1) adequacy and quality of data, (2) degree and type of uncertainty associated with the evidence, and (3) relationship of the evidence to the risk assessment questions. The analysis will be stronger if lines of evidence to be considered can be specified in advance of the analysis.

Risk characterization also involves and ecological characterization. Is the effect associated with a stressor sufficiently serious to cause a significant change in the ecosystem? What level of change is acceptable? Where endpoints are ecological variables that normally vary over a wide range it is important to be able to show that the stressor effect is pushing the variable beyond its normal limits.